

Appn. No.: 10/687,389
Response dated December 12, 2005
Reply to Office Action of August 11, 2005

Amendments to the Specification

Please replace the paragraph number 83, beginning on page 22 of the specification as filed with the following paragraph:

The medical device system may calculate one or more variables that quantify the quality of the neurological signal received from each of the monitoring elements. For each variable, data points of the received neurological signal may be gathered and analyzed within a given moving window. The percentage of data points with associated signal quality variable falling above or below a predetermined range may be determined and monitored as the window moves with time. The resulting percentage values will be numbers between 0 and 100, representing quality, so that the medical system can quantify the quality of each associated window of data points. The medical system may use the computed quality to accept or reject data during monitoring. [.]
Depending on the embodiment of the medical device system, this process may be implemented as software modules within any one of the components of the external system, either the implantable device 953 or the external device 950, or within the implantable system 10. Each quality variable of the received raw neurological signal, or processed signals obtained through some transformation of the neurological signals to be used in subsequent processing, may be continuously and independently monitored. Separate software modules may exist for each quality variable of the signals being monitored.

Appln. No.: 10/687,389
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Please replace the paragraph number 89, beginning on page 25 of the specification as filed with the following paragraph:

As another example, a neurological signal parameter that may be monitored for signal quality is a "mains" artifact, namely an excessive noise at a certain frequency, for example, approximately 60 Hz. Such a signal may be indicative of outside noise interference (e.g., caused by turning on a light bulb ~~lightbulb~~) and may be indicative of a faulty or high-impedance electrode. Of course, the frequency may vary. For example, in European countries, the AC noise interference has a frequency of approximately 50Hz. The medical device system may measure instantaneous amplitudes of the signal and calculate a running average for a given moving window, of 60 seconds duration. Once it is determined that the average frequency or amplitude of the signal is excessive, namely above a predetermined threshold, the medical device can remove the associated electrode from consideration in the data analysis process (e.g., a seizure detection algorithm). Once the average frequency or amplitude of the signal returns below a second (typically lower) predetermined level, the associated electrode may then be brought back into consideration.

Appln. No.: 10/687,389
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Please replace the paragraph number 98, beginning on page 28 of the specification as filed with the following paragraph:

A maximal amount of poor quality data that is tolerable may be qualified using different criterion. Poor quality data may be gauged by a signal power to noise power ratio (S/N) that is associated with neurological data. Also, poor quality data may be gauged by a fraction of the foreground window that contains a noisy signal. Typically, the foreground window is more vulnerable to noise than the background window since the foreground is determined over a shorter time duration. One may also consider different artifacts. Movement artifacts may be detected with accelerometers, in which corresponding outputs may be used to reduce or even cancel the movement artifacts. Other types of artifacts that may be considered include EKG artifacts and disconnection artifacts. EKG artifacts, when recorded from intracranial electrodes, are an indication of high impedance. Disconnection artifacts may be identified by stationary noise in one lead or a set of leads. The characteristics of a baseline that are associated with neurological data may assist in identifying a cause of poor quality data. For example, a flat line without a shift in the baseline and without noise may be indicative that an amplifier has been deactivated or has failed.

Appln. No.: 10/687,389
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Please replace the paragraph number 105, beginning on page 31 of the specification as filed with the following paragraph:

In step 2027, which comprises sub-steps 2029 and 2031, the correctness of electrode placement for seizure detection is verified. In sub-step 2029, the ITEO (investigator time of electrographic onset corresponding to time event 1903 in Figure 19) and the CBOT (clinical behavior onset time corresponding to time event 1907 in Figure 19) are provided to the medical device system. (In the embodiment, step 2027 is optional so that the clinician need not provide ITEO and CBOT to the medical device system.) In sub-step 2031, the medical device system determines if the ITEO did not occur after the CBOT. In the embodiment, the fact that the CBOT occurs before the ITEO is indicative that the selected electrodes are not sufficiently near the focus. In such a case, step 2032 determines whether to stop screening. If so, screening is ended in step 2034. Otherwise, step 2004 allows the physician physician to reposition subdural and/or DBS electrodes. The baseline algorithm monitoring sub-process 2003 is repeated.

Please replace the paragraph number 118, beginning on page 36 of the specification as filed with the following paragraph:

The medical device system may also ensure other efficacy criteria criteria are satisfied for any user-defined treatment therapy configuration. For example, the medical device system providing stimulation therapy may ensure that the polarities of the stimulation pulses are properly defined, e.g., all polarities cannot be off and that the voltage level is greater than zero on at least one stimulation channel, and that at least one cathode and at least one anode are configured.

Appln. No.: 10/687,389
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Please replace the paragraph number 168, beginning on page 54 of the specification as filed with the following paragraph:

In accordance with another feature of the present invention, any one of the above-described medical device systems may be configured so that it may provide hardware and software blanking functionality. In particular, the medical device system may invoke either hardware blanking and/or software blanking of a received neurological signal if the system should not process the signal for the corresponding monitoring element. In the embodiment of the external system 100, for example, hardware blanking (through blanking circuitry 401) corresponds to the system disconnecting the EEG amplifier 103 from the channel that is being stimulated by stimulation electronics 203 through the associated electrode during a time interval that includes the stimulation delivery period. (In the embodiment, amplifier 103 is disconnected from the associated electrode and connected to a reference voltage.) Because no data is being collected during stimulation, no data (for the corresponding channel) is sent to the processor 207 to be processed by the detection algorithm 800 at the associated time. Data may, however, be collected on other channels that are not being stimulated and processed at an associated time.

Appl. No.: 10/687,389
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Please replace the paragraph number 176, beginning on page 57 of the specification as filed with the following paragraph:

Hardware and /or software blanking may be automatically applied based upon the results of applying signal quality control algorithms, such as those described above, to test the reliability of sensor signals. Application of signal quality control may at anytime result in continuous hardware or software blanking of a particular sensor due to artifact. However, signal quality control algorithms may also be applied to any of the sensor channels to determine if the applied therapy (e.g., stimulation) is causing artifacts that require hardware or software blanking during and after application of the therapy. Those sensor channels determined not to be affected by the application of the treatment therapy do not need to be blanked, thus enhancing the ability of the system to monitor the patient. In addition, periodic checking of a sensor channel following a treatment pulse and applying signal quality algorithms can automatically determine the length of time needed for hardware and/or software blanking for that channel during future applications of the therapy. For example, a signal that is associated with an electrode in proximity of a stimulated electrode may be analyzed to have artifact characteristics, including during a time interval in which an artifact affects the signal. Alternatively, parameters of the therapy treatment may be adjusted within a range of values known to be therapeutic in an effort to reduce the effect on the signal quality of adjacent sensors. In this manner the medical device system can enhance its ability to collect data while providing treatment therapy.

Appn. No.: 10/687,389
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Please replace the paragraph number 186, beginning on page 62 of the specification as filed with the following paragraph:

The system may further contain software modules or programs for scoring the severity of sensed neurological signals relating to a nervous system disorder. In particular, the system may monitor sensed neurological signals and compute a relative severity of the events associated with the neurological signal. Thus, each seizure detection may be ranked based on the relative severity score. This process may be performed for each neurological signal that is sensed by the system. Moreover this process may be performed in an implanted device or an external device. If performed in the implanted device, the ranked information may be telemetered to the external device for further processing and/or display.

Please replace the paragraph number 187, beginning on page 62 of the specification as filed with the following paragraph:

A seizure event may include, for example, a detected specified event and a reported event. Examples of a detected specified event include, without limitation, an occurrence of a maximal intensity, an extent of electrographic spread[[]], or a number of detection clusters per unit time exceeding a corresponding predetermined threshold. A detected specified event may be associated with a detection cluster, in which the time duration of the detection cluster or the number of detections within a detection cluster may be further specified. A reported event is a seizure event that the patient perceives and reports, for example, by a button press.